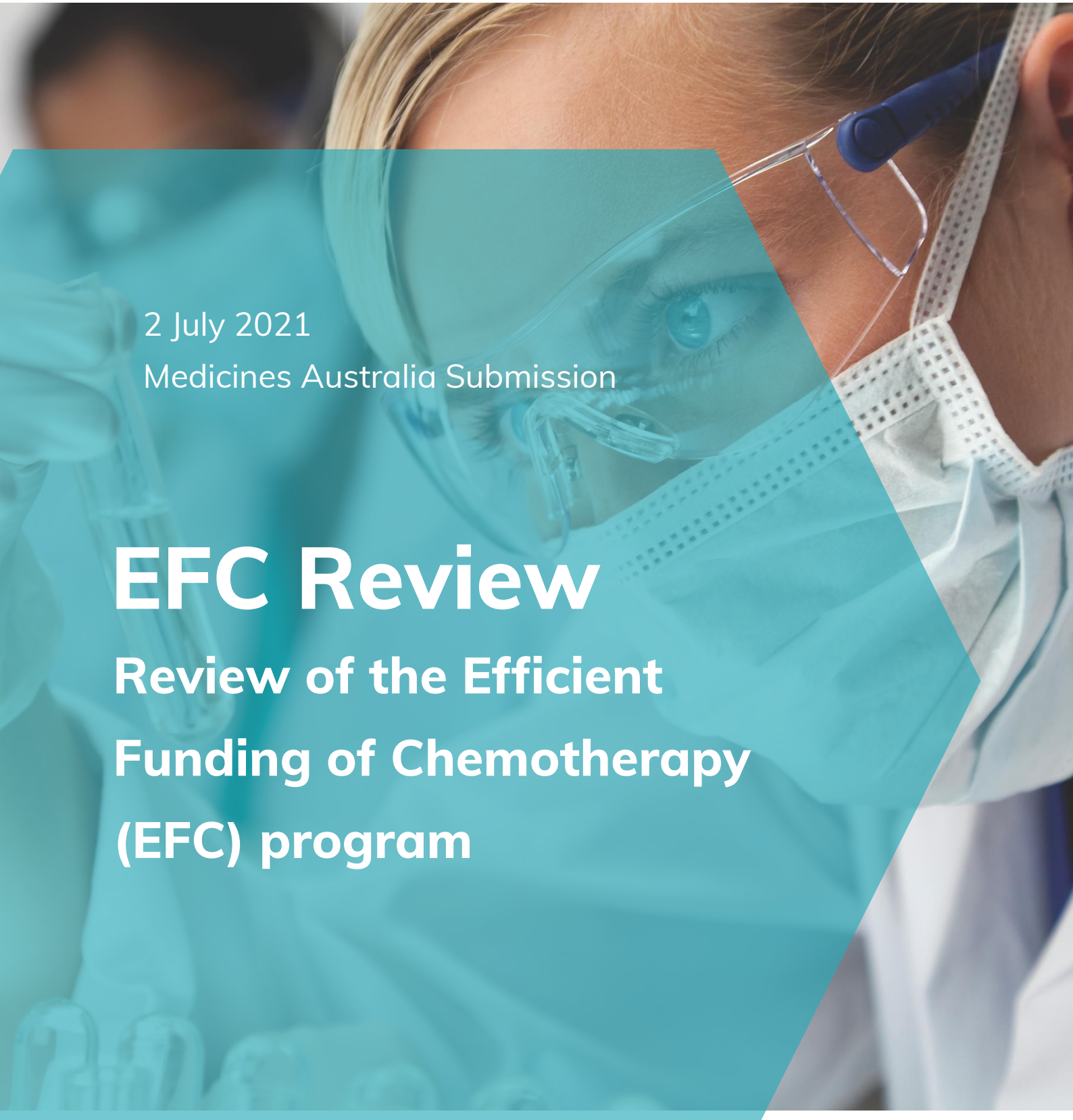


2 July 2021

Medicines Australia Submission

EFC Review

Review of the Efficient Funding of Chemotherapy (EFC) program

Medicines Australia

Introduction

Medicines Australia thanks the Department of Health and Professor Sanchia Aranda for the opportunity to respond to the consultation on the review of Efficient Funding of Chemotherapy (EFC) Program. Medicines Australia is committed to promoting the objectives outlined in the National Medicines Policy (NMP), in particular timely access to the medicines for Australians and Quality Use of Medicines (QUM). In responding to the EFC review, Medicines Australia has focussed its comments on the funding arrangements for chemotherapy services per Sections 5.5 and 5.6 of the discussion paper. Underpinning our recommendations is the need to ensure appropriate access to treatment, reimbursement, remuneration and payment for all chemotherapy providers.

Medicines Australia believes the EFC Program has not remained fit-for-purpose for today's oncology medicines, and must be adapted to ensure it supports patient access to oncology medicines into the future. As such, Medicines Australia recommends that:

- Remuneration should be appropriate, and reflect the provision of services provided and be separated from the cost of oncology drugs;
- Supply chain services should be recognised with a transparent, appropriate fee-for-service that recognises their value; and
- A safety net is needed to ensure Low Volume Self-Compounding Hospitals (LVSCH) are appropriately compensated.

The environment has changed and the EFC Program must be adapted

The last review of EFC arrangements occurred in 2013 and the final report[1] included the following findings:

- There is a high level of complexity with many different models of chemotherapy pharmaceutical service provision, each with differing commercial arrangements between the hospitals, pharmacies and oncologists involved:
    - Economies of scale and location have driven an increased use of out-sourced infusion compounding through commercial third-party compounders.
    - Some of these delivery models involve commercial or equity relationships between pharmacists, oncologists and hospitals.
    - Chemotherapy services have shifted from the public sector to the private sector over time, transferring medicine costs to the PBS.
- Existing funding arrangements do not align with these complex business models

Medicines Australia believes these findings still hold true today and that the funding arrangements are not appropriate and fit-for-purpose. Indeed, the current application of EFC is not aligned with the stated goals of the program to "minimise wastage and reduce cost to patient and the Commonwealth". The current reimbursement provisions under EFC have not in and of themselves improved efficiency and reduced wastage. Where efficiencies and reductions in wastage have been achieved, the benefits have not accrued to the Commonwealth, which is reimbursing for more vials than are actually used.

In addition, we note that the since 2013 the cancer treatment environment has changed. Government has added many more high-value listings to the PBS, including new innovative immunotherapy treatments. EFC coverage has substantially widened to cater for more unmet needs of Australian cancer patients. Through the growing number of high-value EFC medicines and the

[1] https://www1.health.gov.au/internet/main/publishing.nsf/Content/chemotherapy-review/$File/review-of-chemotherapy-funding-arrangements.pdf

increasing efficiency and market share of compounders, the EFC Program costs have increased significantly in recent years.

Medicines Australia also notes the naming of the 'EFC program' may be a source of confusion for stakeholders as it does not include all chemotherapy agents (for example, oral chemotherapies) but also pertains to a broader range of cancer treatments (such as immunotherapy). It may be appropriate to reclassify the description of the current EFC listings to 'infusion related therapy'.

Remuneration is currently not fairly distributed through the supply chain

Wholesalers and Private Providers:

The EFC Program contains examples where remuneration is currently not fairly distributed to oncology supply chain members. These include:

- Remuneration models for the distribution of S100 products, including treatments covered under EFC provisions are out of step with current practices, which increasingly rely on wholesalers. The Government does not pay wholesalers any margin to distribute s100 medicines, including EFC Program medicines. This contrasts with margins paid to wholesalers to distribute s85 medicines to the retail pharmacy sector.
- Private hospitals earning a 1.4% pharmacy mark-up[2] (in addition to other fees), which mean the total administration fee earned by the provider changes depending on the drug cost.

Inconsistencies in fee structures between public and private hospitals further inflate disparities in fees for the same service. Providers should be remunerated appropriately to reflect the nature of the service provided; it should not be influenced by differences in drug costs. Existing mechanisms (e.g. compounder IDs) can be leveraged to ensure the seamless payment of appropriate fees.

Manufacturers and the Commonwealth:

In 2014, the EFC Program introduced algorithms which based reimbursement on the most efficient combination of vials to deliver a prescribed dose of chemotherapy with the objective of minimising wastage and reducing cost to patient and the Commonwealth. Real world practice, particularly with respect to third-party commercial compounders is characterised by "batch compounding" whereby multiple doses of the same chemotherapy regime for multiple patients are prepared on the same day, such that any wastage left over from the preparation of one dose is used to make up the dose for the next patient, a process referred to as "vial sharing". As a result, the total number of vials used to produce the required number of doses is less that what is calculated via the EFC algorithm. Facilities that can batch produce can also take full advantage of the "overage" (the additional volume included in each vial of EFC medicines to ensure that the full dose can be extracted), to further reduce the number of vials required to produce a given number of doses, which is not currently accounted for under the funding of EFC medicines.

Vial sharing, as it is currently practiced, does not provide savings to the Commonwealth because reimbursement is based on an estimation of the most efficient combination of vials required to deliver a specific dose, assuming that any remaining drug is wasted. In practice, any residual drug is used to prepare the next dose for the next patients. Therefore, the total number of vials actually used to produce a given number of doses is less that the number of vials calculated and reimbursed

[2] https://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/pbs-pharmacists/about

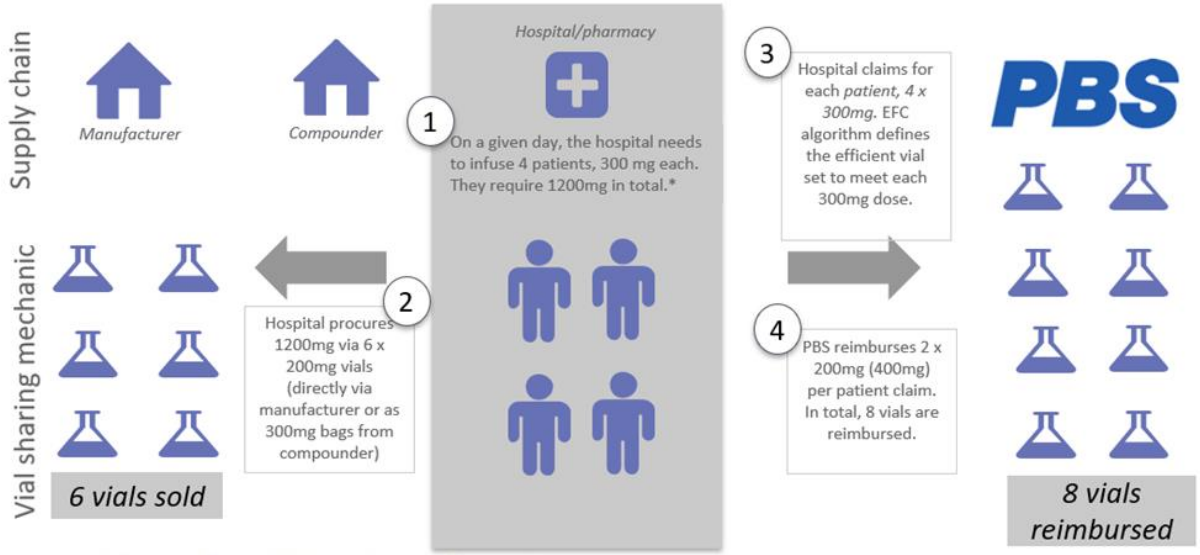
via the EFC algorithm. Consequently, Commonwealth expenditure on the EFC Program is higher than is necessary.

The impact of the differential amount of EFC medicine actually used during the compounding process via vial sharing versus the amount of EFC medicine reimbursed is as follows:

- The Commonwealth provides reimbursement for more vials than are actually used resulting in the Government overpaying for the supply of chemotherapy medicines as compounders can legitimately claim partially used vials multiple times at the full per-vial list price.
- Vial sharing can lead to large differences in the number of vials sold by manufacturers versus the number of vials claimed to have been dispensed and subsequently reimbursed.
    - For products that have a Deed containing a special pricing arrangement (SPA), because rebates are based on Commonwealth expenditure, manufacturers are paying rebates on vials that have not been sold. Ultimately, this has the effect of reducing the price per vial below the cost-effective price agreed between the manufacturer and the Commonwealth.
      This situation is exacerbated for products with a risk sharing arrangement (RSA) because utilisation caps are also based on Commonwealth expenditure. Vial sharing results in Commonwealth expenditure that is above the actual level of utilisation, which can trigger cap breaches and incur further rebates.
- For compounders, extra revenue is generated at the expense of manufacturers and the Commonwealth, through vial sharing, by leveraging the EFC algorithm's inability to properly account for wastage and the use of vial overages.

Medicines Australia reviewed five medicines on behalf of four manufacturers to illustrate the impact of this practice. These medicines represented $551M of Commonwealth Expenditure (2018 CY), out of $1,514M of expenditure for Chemotherapy (EFC & CPAP) in FY 2017/18. The difference in these medications sold by manufacturers compared to that claimed from Government by pharmacy range from 5-33% (average 14%). In all cases, the claims from Government exceeded the volume sold by manufacturers. At the Approved Ex-Manufacturer Price, the value of the total difference in medicine claimed vs sold for these five products was $49.5M. Figure 1 illustrates this issue in more detail.

Figure 1 – the mechanics of vial sharing
Hypothetical example: 4 patients being administered medicine X at hospital Y.
The average dose is 300mg/patient. Vials are available in 200mg units.
Overall, 8 vials are reimbursed compared to 6 purchased.



Remuneration should reflect the provision of services provided and be separated from the cost of the drugs

Medicines Australia proposes that the base funding be calculated on the amount of drug dispensed (per mg) and address additional services/costs associated with administering EFC medicines with appropriate funding that reflects those costs. This approach is consistent with comparable overseas jurisdictions, such as France and Germany.

The benefits of the proposed per-milligram pricing include:

- Patients will continue to receive the correct dose based on weight;
- Compounders will be paid for the amount of chemotherapy they use;
- Manufacturers will be paid the cost-effective price for the amount of chemotherapy they sell;
- Manufacturer rebates will reflect utilisation; and
- Potential savings to Government of approximately $50M per year though better alignment of pharmacy payments with medicines purchased.

It should be noted that per mg reimbursement assumes all wastage is utilised for additional PBS claims. Therefore, only the milligram dose for each patient would be reimbursed, not the whole vial/s, as happens with the current EFC. However, it is likely that in low volume self-compounding hospitals (LVSCH), and for rare cancer treatments, there will be some wastage that will not be able to be used for additional PBS claims. Consequently, a safety net system is needed to ensure that LVSCH are not unfairly impacted by per mg reimbursement. A potential solution could be utilising a 'wastage table' to achieve 100% reimbursement for pharmacy claims for fully utilised vials, and a part payment for the partially used vial required to administer the patient specific dose. This mechanism exists to pay pharmacy for broken packs on the PBS through the current wastage table. An extension of this may be possible for reconstituted medicines. This approach could distinguish between TGA licensed compounding sites where efficiency is higher due to economies of scale. Due to differences in the ability to utilise wastage at a small clinical setting, compared to a large-scale compounder, different wastage table approaches may be required depending on the scale of the compounder. Overall, this solution:

- Aligns the level of reimbursement to the amount of drug dispensed;
- Includes provisions so that LVSCH are not unfairly impacted; and
- Ensures rebates paid by manufacturers accurately reflect in-market utilisation.

Changes in the reimbursement system would require flow-on changes to the HTA process in the way the pricing is evaluated by the PBAC. The PBAC Guidelines stipulate the cost-effective price is based on vial prices using the most efficient combination of vials. That is, price is set fully accounting for wastage. In practice this means the average mg per patient price applied in the cost-effectiveness model using the vial based approach is higher than where an alternative approach, such as a mg based approach (which does not fully incorporate wastage) is used. At a given cost-effective price for the drug, this translates to a lower price per mg using a vial-based approach compared to a mg-based approach[3]. Whilst this is an appropriate mechanism if vial sharing is not allowed, under the current system where vial sharing is the norm, this undervalues the price of the medicine. It should be noted any change to the basis of pricing will necessarily require a corresponding change to various components of the PBAC Guidelines.

[3] https://www.pbs.gov.au/info/industry/useful-resources/manual-pages/4-medicines-medicinal-preparations-or-vaccines

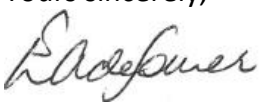
Medicines Australia is ready to work with the Department of Health to ensure any move to introduce per milligram dosing, or the need to introduce a wastage table meets the needs of cancer patients.

Conclusion

In conclusion, Medicines Australia's position is that the EFC Program has not remained fit-for-purpose for today's oncology medicines and should be adjusted to ensure the EFC program supports a future-proof reimbursement system. The provision of services by oncology stakeholders must be recognised by a standardised fee-for-service that reflects the value of a service and distinguishes the cost of medicine from service provision. Smaller hospitals and service providers must not be disadvantaged to ensure patient access is assured.

Medicines Australia welcomes continued engagement on the EFC review. These can be communicated to Medicines Australia's Head of Strategic Policy Implementation, Anne-Maree Englund or to the Manager of Access and Funding, Vincent Tran.

Yours sincerely,



Elizabeth de Somer
Chief Executive Officer

About Medicines Australia

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members discover, develop and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia.

Medicines Australia's members play a vital role in the health of the Australian economy and its citizens. Our members contributed approximately $9 billion to the Australian economy in 2016-17; employ, directly and indirectly, over 23,000 Australians; invest over $1 billion into research and development annually to help 33,000 Australians get early access to emerging innovative therapies. In 2017-18, our industry exported $1.6 billion worth of medicinal products (rising to nearly $4 billion if medicaments are included). None of this, of course, accounts for the additional and largely unquantified benefits to Australian patients' health, wellbeing and the significant economic spill-over effects.

Pharmaceutical companies represented by Medicines Australia have a broad and deep pipeline of innovative medicines, diagnostics, treatments and vaccines. Our members develop, manufacture, and supply critical medicines and vaccines available on the pharmaceutical benefits scheme (PBS), the Life Saving Drugs Program (LSDP), the national immunisation program (NIP) and companion diagnostics or other treatments available through the Medical Benefits Scheme (MBS) and National Blood Authority (NBA). Our membership comprises small, medium, and large Australian and multi-national companies. Many of the world's multi-national medicines manufacturers are members of Medicines Australia through their local affiliates. These local affiliates provide a critical worldwide connection that enables Australians to access globally developed breakthrough medicines and therapies.